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EXAMINER	
DROESCH, KRISTEN L	
ART UNIT	**PAPER NUMBER**
3762	8

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/015,202	OSTROFF ET AL.
	Examiner	Art Unit
	Kristen L Droesch	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-149* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-149* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/5/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 91, and 109 are objected to because of the following informalities: the claim includes "lead system, when the parent claim (41) refers to a lead assembly.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 18-19, 36-38, 55-56 and 73-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Causey III et al. (5,318,591).

Regarding claims 1, and 38, Causey III et al. shows a power supply or current output system comprising a capacitor subsystem (energy storage system) and a battery subsystem (62) (energy source system) electrically coupled to the capacitor subsystem (Col. 2, lines 35-56; Col. 3, lines 21-41).

With respect to claims 18-19, 36-37, 55-56, 73-74, Causey III et al. shows the pacing energy comprises burst or ramp pacing energy (Col. 8, lines 41-45).

4. Claims 1, 8-11, 13, 38, 45-48, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Stein (4,406,286).

Regarding claims 1, and 38, Stein shows a power supply or current output system comprising a capacitor subsystem (17) (energy storage system) and a battery subsystem (energy source system) electrically coupled to the capacitor subsystem (Col. 4, lines 41-43).

Regarding claims 8-11, and 45-48, Stein shows the bi-phasic waveform having a pulse width of approximately 1 ms to approximately 40 ms, approximately 1 ms to approximately 10 ms, approximately 10 ms to approximately 20 ms, and approximately 20 ms to approximately 30 ms (Col. 10, lines 55-58). If the recharge period T_{FR} is set ordinarily at 6-12 ms, the delay interval T_D is 0.5 ms, and the pulse period T_P appears to be shorter than the recharge period T_{FR} in Fig. 3, then the maximum total pulse width of the bi-phasic pulse is 24.5 ms, if it is assumed that the recharge period T_{FR} is set at the maximum of 12 ms and the pulse period T_P is equal to the recharge period T_{FR}, and the minimum total pulse width of the bi-phasic pulse is 6.5 ms, if it is assumed that the recharge period T_{FR} is set at the minimum of 6 ms and the pulse period T_P is negligible.

With respect to claims 13, and 50, Stein shows the bi-phasic waveform comprises a portion that is positive in polarity and a portion that is negative in polarity (Fig. 3)

5. Claims 1-3, 13, 38-40, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Herscovici (4,534,956).

Regarding claims 1, and 38, Herscovici shows a power supply or current output system comprising a capacitor subsystem (energy storage system) and a battery subsystem (energy source system) electrically coupled to the capacitor subsystem (Col. 3, line 63-Col. 4, line 12).

With respect to claims 2-3, and 39-40, Herscovici shows utilizing a bi-phasic pacing pulse having positive and negative portions and a peak current of approximately 1 mA to

approximately 250 mA, approximately 1 mA to approximately 50 mA, (Col. 3, lines 13-45; Col. 63-68).

Regarding claims 13, and 50, Herscovici shows the bi-phasic waveform comprises a portion that is positive in polarity and a portion that is negative in polarity (Fig. 1).

6. Claims 1, 26-27, 31, 38, 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmstrom (5,391,191).

With respect to claims 1 and 38, Holmstrom shows a power supply or current output system comprising a capacitor subsystem (8) and a battery subsystem (6) electrically coupled to the capacitor subsystem (Col. 4, lines 34-37; Figs. 2, 5).

Regarding claims 26-27, and 63-64, Holmstrom shows the pacing energy comprises a monophasic waveform (41) having a pulse width that is approximately 1 millisecond to approximately 40 milliseconds, and approximately 1 millisecond to approximately 10 milliseconds (Col. 6, lines 11-16, and 54-58).

With respect to claim 31, Holmstrom shows the pacing energy comprises a monophasic waveform (41) comprising a negative waveform.

7. Claims 1, 17-18, 35-36, 38, 54-55, 72-73, 75, 91-92, 109-110, 112, 128-129, and 146-147 are rejected under 35 U.S.C. 102(e) as being anticipated by KenKnight (6,148,230).

Regarding claims 1, 38, and 75, KenKnight shows an ICD comprising a housing having an electrically conductive surface on an outer surface of the housing; a lead assembly (20) coupled to the housing which does not directly contact the patient's heart or reside in the intrathoracic blood vessels; a capacitor subsystem located within the housing and electrically coupled to the electrically conductive surface of the electrode and a battery subsystem

electrically coupled to the capacitor subsystem (Col. 1, lines 49-58; Col. 3, lines 60-62; Col. 4, lines 25-28 and 42-50).

With respect to claims 17, 35, 54, 72, 91, 109, 128, and 146, KenKnight shows the lead system comprises an electrode proximate the sternum and anterior to the heart (Col. 3, lines 9-19).

Regarding claims 18, 36, 55, 73, 92, 110, 129, and 147, KenKnight shows the pacing energy comprises burst pacing energy (Col. 2, lines 54-58).

With respect to claim 112, KenKnight shows a method for supplying power for an ICD and for providing pacing energy for an ICD positioned subcutaneously between the third and twelfth rib and using a lead assembly (20) which does not directly contact the patient's heart or reside in the intrathoracic blood vessels comprising generating pacing energy, storing pacing energy, and delivering pacing energy to a patient's heart (Col. 1, lines 49-58; Col. 3, lines 60-62; Col. 4, lines 25-28 and 42-50).

The introductory statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 12, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein (4,406,286). Stein discloses the claimed invention except for the bi-phasic waveform having a

pulse width of approximately 30 ms to approximately 40 ms. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify bi-phasic waveform pulse width as taught by Stein with bi-phasic waveforms having a pulse width of approximately 30 ms to approximately 40 ms, since applicant has not disclosed that these particular bi-phasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-phasic waveform pulse width such as approximately 6.5 ms to approximately 24.5 ms taught by Stein for applying pacing pulses.

10. Claims 14-16, and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein (4,406,286) in view of Florio et al. (6,519,493). Stein is as explained before. Although Stein fails to show the bi-phasic pacing pulses are applied at a rate of approximately 100 to approximately 300 stimuli per minute after the patient's heart rate is greater or equal to 100 beats/minute, attention is directed to Florio et al. who teaches that it is well known to pace the heart at a rate about 5 bpm to 10 bpm greater than a tachycardia rate of 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate (Col. 1, lines 40-54). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply the pacing pulses of Stein at a rate of 155 bpm or more after detection of a tachycardia or 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate.

Regarding claims 16, and 53, it is inherent that Stein and Florio et al. show the biphasic waveform is provided after a patient's heart rate is associated with a monomorphic ECG wave pattern, since polymorphic ECG wave patterns are associated with fibrillation. See Peterson (5,447,519) for definitions of monomorphic and polymorphic ECG patterns.

11. Claims 4-7, 11-12, 41-44, 48-49, 78-81, 85-86, 115-118, and 122-123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herscovici (4,534,956). Herscovici is as explained before.

Regarding claims 4-7, and 41-44, Herscovici discloses the claimed invention except for the bi-phasic waveforms having peak currents of approximately 50 mA to approximately 100 mA, approximately 100 mA to approximately 150 mA, approximately 150 mA to approximately 200 mA, and approximately 200 mA to approximately 250 mA. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the bi-phasic waveform peak currents as taught by Herscovici with bi-phasic waveform peak currents of approximately 50 mA to approximately 100 mA, approximately 100 mA to approximately 150 mA, approximately 150 mA to approximately 200 mA, and approximately 200 mA to approximately 250 since applicant has not disclosed that these particular bi-phasic waveform peak currents provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-phasic waveform peak current such 30 mA taught by Herscovici for pacing the heart.

12. Claims 14-16, and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herscovici (4,534,956) in view of Florio et al. (6,519,493). Herscovici is as explained before. Although Herscovici fails to show the bi-phasic pacing pulses are applied at a rate of approximately 100 to approximately 300 stimuli per minute after the patient's heart rate is greater or equal to 100 beats/minute, attention is directed to Florio et al. who teaches that it is well known to pace the heart at a rate about 5 bpm to 10 bpm greater than a tachycardia rate of 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate (Col. 1, lines 40-54). Therefore, it would have been obvious to one with

ordinary skill in the art at the time the invention was made to apply the pacing pulses of Herscovici at a rate of 155 bpm or more after detection of a tachycardia or 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate.

Regarding claims 16, and 53, it is inherent that Hescovici and Florio et al. show the monophasic waveform is provided after a patient's heart rate is associated with a monomorphic ECG wave pattern, since polymorphic ECG wave patterns are associated with fibrillation. See Peterson (5,447,519) for definitions of monomorphic and polymorphic ECG patterns.

13. Claims 20-25, 28-30, 57-62, 65-67, and 149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmstrom (5,391,191).

With respect to claims 20-25, 57-62, and 149, Holmstrom discloses the claimed invention except for the monophasic waveforms having peak currents of approximately 1 mA to approximately 250 mA, approximately 1 mA to approximately 50 mA, approximately 50 mA to approximately 100 mA, approximately 100 mA to approximately 150 mA, approximately 150 mA to approximately 200 mA, and approximately 200 mA to approximately 250 mA. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform peak currents as taught by Holmstrom with monophasic waveforms having peak currents of approximately 1 mA to approximately 250 mA, approximately 1 mA to approximately 50 mA, approximately 50 mA to approximately 100 mA, approximately 100 mA to approximately 150 mA, approximately 150 mA to approximately 200 mA, and approximately 200 mA to approximately 250 mA, since applicant has not disclosed that these particular monophasic waveform peak currents provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any monophasic waveform peak current such as the monophasic waveform of 2.5 V or 5.0V as taught by

Holmstrom for applying pacing pulses. See Raddi (3,707,974), Bihn et al. (4,290,430), and Callaghan (4,878,497) for examples of prior art monophasic pacing pulses with constant current.

With respect to claims 28-30, and 65-67, Holmstrom discloses the claimed invention except for the monophasic waveforms having pulse widths between approximately 10 milliseconds and approximately 20 milliseconds, approximately 20 milliseconds and approximately 30 milliseconds, and approximately 30 milliseconds and approximately 40 milliseconds. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform pulse widths as taught by Holmstrom with monophasic waveforms having pulse widths between approximately 10 milliseconds and approximately 20 milliseconds, approximately 20 milliseconds and approximately 30 milliseconds, and approximately 30 milliseconds and approximately 40 milliseconds, since applicant has not disclosed that these particular monophasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any monophasic waveform pulse width such as approximately 1 millisecond as taught by Holmstrom for applying pacing pulses.

14. Claims 32-34, and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmstrom (5,391,191) in view of Florio et al. (6,519,493). Holmstrom is as explained before. Although Holstrom fails to show the monophasic pacing pulses are applied at a rate of approximately 100 to approximately 350 stimuli per minute after the patient's heart rate is greater or equal to 100 beats/minute, attention is directed to Florio et al. who teaches that it is well known to pace the heart at a rate about 5 bpm to 10 bpm greater than a tachycardia rate of 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate (Col. 1, lines 40-54). Therefore, it would have been obvious to one with

ordinary skill in the art at the time the invention was made to apply the pacing pulses of Holmstrom at a rate of 155 bpm or more after detection of a tachycardia of 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate.

Regarding claims 35, and 71, it is inherent that Holmstrom and Florio et al. show the monophasic waveform is provided after a patient's heart rate is associated with a monomorphic ECG wave pattern, since polymorphic ECG wave patterns are associated with fibrillation. See Peterson (5,447,519) for definitions of monomorphic and polymorphic ECG patterns.

15. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holmstrom (5,391,191) in view of Kieval (5,800,464). Holmstrom is as explained before. Although Holstrom fails to show the monophasic pacing pulses comprise a positive voltage portion, attention is directed to Kieval who shows applying monophasic pacing pulses with a positive portion in order to hyperpolarize the cardiac cells and enhance cardiac function. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the monophasic pacing pulses of Holstrom with monophasic pacing pulses with a positive portion as Kieval teaches in order to hyperpolarize the cardiac cells and enhance cardiac function.

16. Claims 93, 111, 130, and 148 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Causey III et al. (5,318,591). KenKnight is as explained before. Although KenKnight fails to show the pacing energy comprises ramp pacing energy, attention is directed to Causey III et al. which teaches ramp pacing energy is well known (Col. 1, lines 32-41). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize ramp pacing energy since it is well known in the art.

17. Claims 82-86, and 119-123 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Stein (4,406,286). Although KenKnight fails to show utilizing a bi-phasic pacing pulse, attention is directed to Stein who shows utilizing a bi-phasic pacing pulses having a positive and negative pulse a duration of from approximately 2 ms to approximately 40 ms (Fig. 3; Col 4, lines 2-7, lines 41-43; Col. 6, lines 51-66). Stein teaches that utilizing bi-phasic waveforms reduces stimulation levels at the input of sense amplifiers (Col. 2, line 64 - Col. 3, line 2). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize bi-phasic pacing pulses having a positive and negative pulse a duration of from approximately 2 ms to approximately 40 ms, in order to reduce stimulation levels at the input of sense amplifiers.

With respect to claims 85-86, and 122-123, KenKnight and Stein disclose the claimed invention except for the bi-phasic waveforms having pulse widths between approximately 20 ms and approximately 30 ms, and approximately 30 ms and approximately 40 ms. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify bi-phasic waveform pulse widths as taught by KenKnight and Stein with bi-phasic waveforms having pulse widths between approximately 20 ms and approximately 30 ms, and approximately 30 ms and approximately 40 ms, since applicant has not disclosed that these particular bi-phasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-phasic waveform pulse width such as approximately 6.5 ms to approximately 24.5 ms taught by KenKnight and Stein for pacing the heart.

18. Claims 76-81, 77, 85-90, 113-118, and 122-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Herscovici (4,534,956). Although

KenKnight fails to show utilizing a bi-phasic pacing pulse, attention is directed to Herscovici who shows utilizing a bi-phasic pacing pulse having positive and negative portions and a peak current of approximately 1 mA to approximately 250 mA, approximately 1 mA to approximately 50 mA (Col. 3, lines 13-45; Col. 63-68). Herscovici teaches that utilizing a bi-phasic waveform allows sensing of an evoked response of the heart because the electrical charges are balanced by using a bi-phasic waveform (Col. 1, line 9-Col. 2, line 36). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize a bi-phasic pacing pulse having a positive and negative pulse and a peak current of approximately 1 mA to approximately 250 mA, approximately 1 mA to approximately 50 mA as Herscovici teaches in order to enable sensing of an evoked response due to the electrical charge balance by using a bi-phasic waveform.

Regarding claims 78-81, and 115-118, KenKnight and Herscovici disclose the claimed invention except for the bi-phasic waveforms having peak currents of approximately 50 mA to approximately 100 mA, approximately 100 mA to approximately 150 mA, approximately 150 mA to approximately 200 mA, and approximately 200 mA to approximately 250 mA. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the bi-phasic waveform peak currents as taught by KenKnight and Herscovici with bi-phasic waveform peak currents of approximately 50 mA to approximately 100 mA, approximately 100 mA to approximately 150 mA, approximately 150 mA to approximately 200 mA, and approximately 200 mA to approximately 250 since applicant has not disclosed that these particular bi-phasic waveform peak currents provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-

phasic waveform peak current such 30 mA taught by KenKnight and Herscovici for pacing the heart.

With respect to claims 85-86, and 122-123, KenKnight and Herscovici disclose the claimed invention except for the bi-phasic waveform having a pulse width between approximately 20 ms and approximately 30 ms, and approximately 30 ms and approximately 40 ms. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify bi-phasic waveform pulse widths as taught by KenKnight and Herscovici with bi-phasic waveforms having pulse widths between approximately 20 ms and approximately 30 ms, and approximately 30 ms and approximately 40 ms, since applicant has not disclosed that these particular bi-phasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any bi-phasic waveform pulse width such as approximately 5.5 ms to approximately 19.8 ms taught by KenKnight and Herscovici for pacing the heart.

19. Claims 88-90, and 125-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Herscovici (4,534,956) and further in view of Florio et al. (6,519,493). KenKnight and Herscovici is as explained before. Although KenKnight and Herscovici fail to show the bi-phasic pacing pulses are applied at a rate of approximately 100 to approximately 300 stimuli per minute after the patient's heart rate is greater or equal to 100 beats/minute, attention is directed to Florio et al. who teaches that it is well known to pace the heart at a rate about 5 bpm to 10 bpm greater than a tachycardia rate of 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate (Col. 1, lines 40-54). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply the pacing pulses of KenKnight and Herscovici at a rate of

155 bpm or more after detection of a tachycardia or 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate.

Regarding claims 90, and 127, it is inherent that KenKnight, Hescovici and Florio et al. show the monophasic waveforms are provided after a patient's heart rate is associated with a monomorphic ECG wave pattern, since polymorphic ECG wave patterns are associated with fibrillation. See Peterson (5,447,519) for definitions of monomorphic and polymorphic ECG patterns.

20. Claims 94-105, and 131-142 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Holmstrom (5,391,191).

With respect to claims 100-101, 105, 137-138, and 142, although KenKnight fails to show utilizing monophasic pacing pulses, attention is directed to Holmstrom who shows utilizing monophasic pacing pulses having a negative polarity and a duration of approximately 1 millisecond to approximately 40 milliseconds and approximately 1 milliseconds to approximately 40 milliseconds, (Col. 6, lines 11-16, and 54-58; Figs. 2, 5). Holmstrom teaches that utilizing a monophasic waveform stimulation pulses consumes half the current that biphasic stimulation pulses of the same amplitude and duration consume (Col. 6, lines 40-68). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize monophasic pacing pulses having a duration of approximately 1 millisecond to approximately 40 milliseconds and approximately 1 milliseconds to approximately 40 milliseconds as Holmstrom teaches since utilizing a monophasic waveform stimulation pulses consumes half the current that biphasic stimulation pulses of the same amplitude and duration consume.

With respect to claims 94-99, and 131-136, KenKnight and Holmstrom disclose the claimed invention except for the monophasic waveforms having peak currents of approximately 1 mA to approximately 250 mA, approximately 1 mA to approximately 50 mA, approximately 50 mA to approximately 100 mA, approximately 100 mA to approximately 150 mA, approximately 150 mA to approximately 200 mA, and approximately 200 mA to approximately 250 mA. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform as taught by KenKnight and Holmstrom with monophasic waveforms having peak currents of approximately 1 mA to approximately 250 mA, approximately 1 mA to approximately 50 mA, approximately 50 mA to approximately 100 mA, approximately 100 mA to approximately 150 mA, approximately 150 mA to approximately 200 mA, and approximately 200 mA to approximately 250 mA, since applicant has not disclosed that these particular monophasic waveform peak currents provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any monophasic waveform peak current such as the monophasic waveform of 2.5 V or 5.0V as taught by KenKnight and Holmstrom for applying pacing pulses. See Raddi (3,707,974), Bihn et al. (4,290,430), and Callaghan (4,878,497) for examples of monophasic pacing pulses with constant current

Regarding claims 102-104, and 139-141, KenKnight and Holmstrom disclose the claimed invention except for the monophasic waveform having a pulse width between approximately 10 milliseconds and approximately 20 milliseconds, approximately 20 milliseconds and approximately 30 milliseconds, and approximately 30 milliseconds and approximately 40 milliseconds. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform

pulse widths as taught by KenKnight and Holmstrom with monophasic waveforms having pulse widths between approximately 10 milliseconds and approximately 20 milliseconds, approximately 20 milliseconds and approximately 30 milliseconds, and approximately 30 milliseconds and approximately 40 milliseconds, since applicant has not disclosed that these particular monophasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any monophasic waveform pulse widths such as approximately 1 millisecond as taught by KenKnight and Holmstrom for applying pacing pulses.

21. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Holmstrom (5,391,191) and further in view of Kieval (5,800,464). Holmstrom is as explained before. Although KenKnight and Holstrom fails to shows the monophasic pacing pulses comprise a positive voltage portion, attention is directed to Kieval who shows applying monophasic pacing pulses with a positive portion in order to hyperpolarize the cardiac cells and enhance cardiac function. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the monophasic pacing pulses of KenKnight and Holstrom with monophasic pacing pulses with a positive portion as Kieval teaches in order to hyperpolarize the cardiac cells and enhance cardiac function.

22. Claims 106-108, and 143-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Holmstrom (5,391,191) and further in view of Florio et al. (6,519,493). KenKnight and Holmstrom are as explained before. Although KenKnight and Holmstrom fail to show the monophasic pacing pulses are applied at a rate of 100 to approximately 350 stimuli per minute after the patient's heart rate is greater or equal to 100 beats/minute, attention is directed to Florio et al. who teaches that it is well known to pace the

heart at a rate about 5 bpm to 10 bpm greater than a tachycardia rate of 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate (Col. 1, lines 40-54). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply the pacing pulses of KenKnight and Holmstrom at a rate of 155 bpm or more after detection of a tachycardia of 150 bpm or more in order to overdrive the heart rate and slowly reduce the hear rate back to a normal resting rate.

Regarding claims 108, and 145, it is inherent that KenKnight, Holmstrom and Florio et al. show the monophasic waveform is provided after a patient's heart rate is associated with a monomorphic ECG wave pattern, since polymorphic ECG wave patterns are associated with fibrillation. See Peterson (5,447,519) for definitions of monomorphic and polymorphic ECG patterns.

Double Patenting

23. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Applicant is advised that should claims 17-19, 54-56, 91-93, and 128-130 be found allowable, claims 35-37, 72-74, 109-111, and 146-148 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

26. Claims 1, 26-37, 75, 100-112, and 137-148 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 7-12, 15-20, 41, 47-52, 55-61, 67-72, and 75-80 of copending Application No. 10/011958. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

27. Claims 1, 26-37, 75, 100-112, and 137-148 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-12, 33, 40-44, 49, and 55-60 of copending Application No. 10/011860. Although the conflicting claims are not identical, they are not patentably distinct from due to the fact that the only claimed difference is intended use. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kerver et al. (5,964,787) shows a pacer that generates bi-phasic stimulation pulses.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

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